

**K242865 Syncem Hip Spacer**Jun 12, 2025  
265 days to decisionK242865 · Product code: **KWL** · Orthopedic  
Source: <https://www.510kdatabase.net/k242865/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal (KWL)
Date received	Sep 20, 2024
Decision date	Jun 12, 2025
Days to decision	265 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Syncem Knee Spacer; Syncem Shoulder Spacer

**APPLICANT**

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Company	<b>Biocomposites, Ltd.</b>
Location	Keele, GB
Contact	Melisa Lamanna
Website	<a href="https://www.biocomposites.com">https://www.biocomposites.com</a>
510(k) history	27 submissions · 27 cleared · 2000-2026

Biocomposites, Ltd. is an international medical device manufacturer based in Keele, GB. The company engineers and manufactures specialized devices for musculoskeletal infection, trauma, spine, and orthopedic applications. Biocomposites has received FDA 510(k) clearances from total submissions since 2000. The company's portfolio is dominated by Orthopedic devices, which represent 89% of its regulatory submissions. The latest FDA 510(k) clearance was granted in 2026, confirming active regulatory engagement. The company's core product lines include antibiotic-loaded bone cem...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k242865/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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